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510(k) Summary**K970021**

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1. Submitter Name, Address, and Date of Submission:

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Rüsch International
Tall Pines Park
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Contact: Same as above.

2. Names of the Device, Common, Proprietary(if Known), and Classification.

Classification Name: Suprapubic Catheter and Accessories

Common Name: Suprapubic Catheter Kit

Proprietary Name: Rüsch Suprapubic Tray

3. Identification of the legally marketed device to which the submitter claims equivalence.

The Rüsch Suprapubic Tray is substantially equivalent in design and function to the Rüsch SupraFoley Suprapubic Introducer and Foley Catheter, Rüsch Simplastic Suprapubic Catheter, Microvasive Percutaneous Suprapubic Balloon Catheter Set, and the Cook Stamey Percutaneous Catheter Set and the Rüsch Suprapubic Catheters.

4. Description of the Device:

The kit consists of two major components: silicone catheter and plastic introducer assembly, along with attachment tape to fix the catheter to the skin, if required, and an optional scalpel. The kit is used for percutaneous bladder drainage. There are two types of silicone catheters. The first comes equip with one pair of drainage eyes. The second type of silicone catheter comes with six drainage eyes arranged in a pigtail shape.

5. Intended Use of the Device:

The kit is used for percutaneous bladder drainage and to drain fluids to and from the urinary tract.

The usage of this product is identical to previous devices, which have the same technological characteristics.

6. Summary of Technological Characteristics:

The following technological characteristics are the same or equivalent as predicate devices:

The kit consists of introducer system for the catheter, which provides the pathway for percutaneous insertion. One introduced the introducer system is removed, the catheter remaining provides the conduit for fluid passage to and from the urinary tract.

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